K120441

510(k) SUMMARY

MAY 3 1 2012

Getinge 700HC-E Series Steam Sterilizer

Submitted by:	Getinge Sourcing LLC 1777 E Henrietta Road Rochester, NY 14623-3133
Contact Person:	Barb Smith, RAC Sr. Manager, Regulatory Affairs Phone: (585) 214-6049 Fax: (585) 272-5299
Date prepared:	February 6, 2012
Proprietary Name:	Model 700HC-E Series Steam Sterilizer
Common Name:	Steam Sterilizer
Device Classification:	Steam Sterilizer (80 FLE) Class II, as listed per 21 CFR 880.6880
Predicate Device:	Getinge Model 400HC/500HC Series Steam Sterilizer [K103504]

Description of Device:

The Getinge 700HC-E Series Steam Sterilizer is designed for sterilization of heat and moisture stable materials used in healthcare facilities. The only model designation provided in the 700HC-E Series Steam Sterilizer is 733HC-E. The model 733HC-E is available in 3 chamber sizes; 39 inches long (21.5 cu ft), 53 inches long (29.3 cu ft) and 61 inches long 33.7 cu ft).

The 733HC-E Steam Sterilizer employs both gravity/downward displacement with positive pulse conditioning and pressure/vacuum pulsing for dynamic air removal. Up to 22 cycles can be easily accessed and custom cycle names can be designated by the user (duplicate cycles are provided to allow for user designated names). All cycle phases are sequenced and monitored by the control system, providing both audible and visual notification of deviation from certain operating parameters.

List of available cycles:
Model 733HC-E Steam Sterilizer Cycles and Load Chart

Cycle Type	No. of Cycles	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Length		
		Exp. Temp.	Exp. Time	Drying Time		1.00 m (39 in.)	1.35 m (53 in.)	1.55 m (61 in.)
vac PREVAC	5	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	10	15	20
					Fabric Packs	24	32	48
vac PREVAC 2	3	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric Packs	24	32	48
vac PREVAC 4	1	132.2°C (270.0°F)	4 min	16 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	10	15	20
					Fabric packs	24	32	48
vac PREVAC 5	1	132.2°C (270.0°F)	4 min	3 min (Note 4)	Fabric packs	24	32	48
vac B & D TEST	1	133.9°C (273.0°F)	3 min, 30 sec	0 min	S.M.A.R.T. Pack or equivalent (1 max.) in an EMPTY chamber	1 Test Pack	1 Test Pack	1 Test Pack
grv GRAVITY 1	4	121.1°C (250.0°F)	30 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	10	15	20
					Fabric packs	24	32	48
grv GRAVITY 2	3	135.0°C (275.0°F)	10 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	10	15	20
					Fabric packs	24	32	48
grv GRAVITY 3	1	132.2°C (270.0°F)	10 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	10	15	20
					Fabric packs	24	32	48

ius IMMEDUSE 1 (Notes 1, 7)	1	135.0°C (275.0°F)	3 min	30 sec (Note 4)	Unwrapped, nonporous instrument trays, up to 11.3 kg (25.0 lb) (per tray)	3	3	3
liq LIQUIDS 1	1	121.1°C (250.0°F)	30 min	5.17 kPa/min (0.75 psi/min) (Note 3)	Each container 1000 mL (34 fl oz) or smaller (Notes 5, 6, 8)	112	154	196
liq LIQUIDS 2	1	121.1°C (250.0°F)	45 min	5.17 kPa/min (0.75 psi/min) (Note 3)	Each container 1000 mL (34 fl oz) or smaller (Notes 5, 6, 8)	112	154	196
lk LEAK TEST (Note 2)	1	131.1°C (268.0°F)	3 min.	15 min dry, 5 min equalize, 15 min test	Empty Chamber (other than loading accessories)	–	–	–

NOTE: Liquid Cycles are not intended for the sterilization of liquids used for direct patient contact.

TABLE NOTES:

1. The load configurations listed in these tables are those used during testing validations of the sterilizer. These configurations follow *AAMI Standard ST8: Hospital steam sterilizers* where applicable (fabric packs are process challenge devices as described in ANSI/AAMI ST8 and were made to be consistent with the packs described in ANSI/AAMI ST8). For guidance on processing loads in the sterilizer, refer to *AAMI Standard ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

2. Vacuum leak test parameters are not adjustable.

3. Cooldown rate

4. Items may NOT be dry at the end of the following cycles:
   - IMMEDUSE 1
   - PREVAC2
   - PREVAC5

   Drying time may be added if required.

5. Your facility must validate the cycle if the load includes containers larger than 1000 mL (34 fl oz).

6. Use vented or open containers only.

7. The recommended minimum exposure time and temperature for unwrapped, nonporous loads (e.g., metal instruments) that are sterilized for immediate use is 3 minutes at 135°C (275°F).

8. A small load of 1000mL (34 fl oz) containers requires an exposure time of 45 min.

Intended Use:

The Getinge 700HC-E Series Steam Sterilizer is intended for use by health care facilities and to be used to sterilize wrapped and unwrapped porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam.

Comparisons to Predicate Device:

Similarities between the Getinge 700HC-E Series Steam Sterilizer and the identified predicate are:

- Intended use is the same: Intended for use by health care facilities to sterilize wrapped and unwrapped, porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam.

- Operating Principle is the same: Saturated steam is the sterilizing agent.

- Materials of construction are the same: Vessel material is Stainless Steel SA240-316Ti. There is no direct patient contact associated with this device.

- Cycle Types: The cycle types offered are the same; Prevac (135°C, 132°C), Gravity (121°C, 132°C, 135°C), Immediate Use (135°C) and Liquids 121°C (not for sterilization of liquids used directly for patient contact).

- Performance Testing: Factory recommended cycles were tested per industry standards and guidelines and effectiveness of sterilizer function was demonstrated by complete kill of biological indicators. Getinge Sterilizers have been validated to meet the requirements of ANSI/AAMI ST8:2008 Hospital Steam Sterilizers.

The differences between the Getinge 700HC-E Series Steam Sterilizer and the predicate device (Getinge 400HC/500HC Series Steam Sterilizer) are:

- The Getinge 700HC-E Series Steam Sterilizer has larger vessel sizes. Because of the larger vessel size the chamber closure (door operation and door retaining method) are different. Also the larger chamber sizes require different piping and steam to chamber design to accommodate the increased chamber volume. The larger chamber size also allows for larger loads to be processed. Factory recommended maximum load sizes are tested for effectiveness and clearly identified in product labeling.

- The Getinge 700HC-E Series Steam Sterilizer has an updated larger display. The updated display provides four run screen formats as opposed to three and allows the user to interact with the controls by means of a touch screen.

Summary of Performance Testing:

Factory recommended cycles were tested per industry standards and guidelines and effectiveness of sterilizer function was demonstrated by complete kill of biological indicators. Getinge Sterilizers have been validated to meet the requirements of ANSI/AAMI ST8:2008 Hospital Steam Sterilizers.
The results of Getinge 700HC-E Series Steam Sterilizer validation testing demonstrate that the sterilizer performs as intended. Summary of testing:

- Empty chamber testing performed for all cycles as described in ANSI/AAMI ST8:2008 Hospital Steam Sterilizers section 5.4.2.5. The results demonstrated that the sterilizer is capable of providing steady-state thermal conditions within the chamber that are consistent with the predicated sterility assurance level (SAL) in the load.

- All PREVAC and GRAVITY cycles were validated using fabric process challenge packs as described in ANSI/AAMI ST8:2008 section 5.5.2. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and moisture retention of less than 3% increase in pre-sterilization test pack weight including no visible wet spots.

- All PREVAC (excluding PREVAC 2 and PREVAC 5 that have shortened drying times) and GRAVITY cycles were validated using wrapped instrument process challenge devices as described in ANSI/AAMI ST8:2008 section 5.5.4. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and moisture retention of less than 20% increase in pre-sterilization weight of the towel including no visible wet spots on the outer wrapper.

- All Immediate Use (Flash) cycles were validated using a unwrapped non-porous process challenge device as described in ANSI/AAMI ST8:2008 section 5.5.5. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12 and complete BI kill.

- Liquid loads cycles were validated using 3 one liter flasks as described in ANSI/AAMI ST8:2008 section 5.5.3. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and water loss not exceeding 50ml.

- Bowie Dick cycle was validated using the Bowie-Dick test pack as described in ANSI/AAMI ST8:2008 section 5.6.1.1.

- The software validation for the cycle operation was performed according to FDA guidance document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (5/11/2005)*".

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The 700HC-E Series Steam Sterilizer has the same intended use and technological characteristics as the predicate device. The 700HC-E Series Steam Sterilizer meets the applicable requirements of AAMI ST8:2008 performance standards. Based on the information provided in this premarket notification, it can be concluded that the subject device is substantially equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Barb Smith
Senior Manager Regulatory Affairs
Getinge Sourcing, LLC
1777 East Henrietta Road
Rochester, New York 14623-3133

MAY 31 2012

Re: K120441
Trade/Device Name: Getinge 700HC-E Series Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam sterilizer
Regulatory Class: II
Product Code: FLE
Dated: May1, 2012
Received: May 2, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120441

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Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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